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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,767	05/14/2001	Isao Horiuchi	HORIUCHI-6	9992

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,767

Applicant(s)

HORIUCHI, ISAO

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1617

DETAILED ACTION

Claims 1-8 are pending.

Specification

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for papain and bromelain, does not reasonably provide enablement for all proteases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without

Art Unit: 1617

undue experimentation wherein patients susceptible to having symptoms of a disorder or dysfunction are treated with the claimed invention.

The number of known proteases is immeasurable, and each day new ones are discovered. Thus, in order to determine which proteases, out of all the known proteases, work in the instant invention, a great deal of time and experimentation would be required. While the instant specification does provide guidance and working examples for utilizing papain and bromelain as proteases in cosmetic compositions, the specification does not provide guidance or working examples for other specific proteases useful in the invention. As disclosed by Lee et al. (4,524,136), one of skill in the art would know that papain and bromelain and a few other proteases, can be used in cosmetic compositions, but would not know what properties made some proteases useful in cosmetic compositions and others not useful. Furthermore, while a great number of proteases are physically known, their chemically properties are not necessarily known. Hence, it would be impossible for the skilled artisan in the cosmetic art to be apprised of every protease that works in the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "culture supernatant" in claims 1 (lines 1-2) is vague and indefinite, as it is not clear what chemical substituents are encompassed by this phrase. The specification does not

Art Unit: 1617

define this phrase and one of ordinary skill in the art would not be apprised of all the possible chemical substituents encompassed by this phrase.

(ii) The phrases “protease derived from *Agaricus blazei* Murlil”, “protease derived from *Grifola frondosa*”, “protease derived from *Bacillus natto*” in claims 4-6, are vague and indefinite, as the metes and bounds of the claims are not clearly defined. The specification does not define what these proteases these are and one of ordinary skill in the art would not be apprised of what proteases are encompassed by this phrase.

(iii) The phrase “wherein said lactic acid bacteria are lactic acid bacteria for fermenting kefir” in claim 7 is rejected, because the compound in these claims is not defined with any chemical or physical characteristic, but only by functional properties. A claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention. Thus, the scope is indefinite. See *ex parte Pulvari* (POBA 1966) 157 USPQ 169.

(iv) Claim 8 is vague and indefinite, as it is confusing. What are the one or more materials mixed with? What is the relationship between the composition in claim 1 and the materials in claim 8?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1617

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (4,524,136).

Lee et al. teach a process for preparing a cosmetic composition having a moisturizing effect in which lactic acid and casein hydrolysate formation are carried out simultaneously in skim milk by lactic acid bacteria and proteases. See Example 1, wherein after sterilizing skim milk, 2-3% of *L. bulgaricus*, 0.8% of bacterial neutral protease of *Bacillus subtilis*, and 0.6% of acid protease of *Aspergillus* are added to the solution. The composition is then heated, cooled, filtered, and pH modified. The composition is added to water as a carrier. See Col. 1, line 19-Col. 2, line 18; col. 3, lines 1-50; Col. 4, line 60-Col. 6, line 68.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru et al. (JP 05-017363) in view of Reiko (JP 02-188531) in further view of Bloching et al. (4,142,999).

Minoru et al. teach cosmetic composition comprising *Lactobacillus* as the active ingredients, wherein the bacterial cells are obtained by culturing, collecting and washing of lactic acid bacterial cells according to ordinary methods. The reference lacks proteases. See abstract.

Reiko teaches cosmetic compositions containing papain and citric acid. See abstract.

Art Unit: 1617

Bloching et al. teach compositions comprising proteases for cleaning and washing. Papain and bromelain are disclosed as proteases. See Col. 1, lines 55-68; Col. 3, lines 55-Col. 5, line 35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Minoru et al. with the composition of Reiko because a) Minoru et al. and Reiko both teach skin care compositions directed toward preventing the appearance of spots and wrinkles, and it is obvious to combine two compositions taught by the prior art to be useful the same purpose to form a third compositions that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the papain of the combined references for bromelain because the combined references and Bloching et al. are both directed to compositions comprising proteases that are applied to the skin, and Bloching et al. teach papain and bromelain as interchangeable proteases for compositions of cosmetic utility.

Claims 1 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru et al. in view of Reiko in further view of Masayuki et al. (JP 07-010734).

Minoru et al. is applied as discussed above. The reference lacks proteases and lactic acid bacteria for fermenting kefir.

Reiko is applied as discussed above.

Masayuki et al. teach cosmetics, wherein kefia granules are cultured by lactic acid bacteria. See abstract.

Art Unit: 1617

The combination of Minoru et al. and Reiko is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the lactic acid bacteria of the combined references for that of Masayuki because a) both teach cosmetic compositions wherein lactic acid bacteria is the active agent and safe for skin, and Masayuki teaches his lactic acid bacteria as exhibiting storage stability.

Claims 1-2, 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru et al. in view of Reiko in further view of JP '11199429 or in further view of JP-6080579 or in further view of Minosasa et al.(JP01125216).

Minoru et al. is applied as discussed above. The reference lacks proteases.

Reiko is applied as discussed above.

JP '492 teach anti-inflammatory skin cosmetics comprising a culture filtrate of *Agaricus blazei*. See abstract.

JP '579 teaches a cosmetic prepared by culturing soy bean with *Bacillus natto* and extracting. See abstract.

Minosasa et al. teach a cosmetic skin care composition comprising extracts of *Grifola frondosa* that provide benefit to the skin. See abstract.

Minoru et al. and Reiko is combined as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the proteases of the combined references as derived from *Agaricus blazei* Murril, *Grifola frondosa* or *Bacillus natto*, as disclosed by JP'429, JP'579, and Minosasa et al., respectively, because a) the combined references, JP '429, JP '479, and Minosasa et al. are all directed to cosmetic compositions possessing beautifying skin benefits; thus, since JP '429,

Art Unit: 1617

JP'479, and Minosasa et al. all teach extracts of *Bacillus natto*, *Grifola frondosa*, and *Agaricus blazei*, respectively, as possessing excellent benefits when applied to skin, it would have been obvious to one of ordinary skill in the cosmetic art to teach the proteases of the combined references as being extracted from JP '429, JP '479, or Minosasa et al.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, there are no unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.


Application/Control Number: 09/831,767

Page 9

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 14, 2002


RUSSELL TRAVERS
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